



Jpw

**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q90669

Yoshifumi TAKENOBU, *et al.*

Appln. No.: 10/551,755

Group Art Unit: 1621

Confirmation No.: 1688

Examiner: Unknown

Filed: October 3, 2005

For: REMEDY FOR SPINAL CANAL STENOSIS

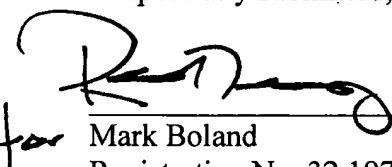
**SUBMISSION OF ENGLISH TRANSLATION OF  
INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As stated in the new application transmittal letter filed October 3, 2005, it is assumed that a copy of the International Preliminary Examination Report (IPER) has been or will be supplied directly by the International Bureau. For the examiner's convenience, however, an English translation of the IPER (Form PCT/IB/338 and Form PCT/ISA/237) is submitted herewith.

Respectfully submitted,

  
for Mark Boland  
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CUSTOMER NUMBER

Enclosures: English translation of IPER (Form PCT/IB/338 and Form PCT/ISA/237)

Date: AUG 29 2006

From the INTERNATIONAL BUREAU

## PCT

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

OHIE, Kunihisa  
Ohie Patent Office  
Selva-Ningyocho 6F  
14-6, Nihonbashi-Ningyocho  
2-chome  
Chuo-ku, Tokyo 103-0013  
JAPON

06. 3. 20

Date of mailing (day/month/year) 09 March 2006 (09.03.2006)	
Applicant's or agent's file reference ONF-4933PCT	
International application No. PCT/JP2004/004836	International filing date (day/month/year) 02 April 2004 (02.04.2004)
Applicant ONO PHARMACEUTICAL CO., LTD. et al	

## IMPORTANT NOTIFICATION

## I. Transmittal of the translation to the applicant.

- The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).
- The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 90 90

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference ONF-4933PCT	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/JP2004/004836	International filing date ( <i>day/month/year</i> ) 02 April 2004 (02.04.2004)	Priority date ( <i>day/month/year</i> ) 03 April 2003 (03.04.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ONO PHARMACEUTICAL CO., LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44bis.1(a).																								
2. This REPORT consists of a total of 6 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3. This report contains indications relating to the following items:  <table> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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<input type="checkbox"/>	Box No. IV	Lack of unity of invention																						
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																						
<input type="checkbox"/>	Box No. VI	Certain documents cited																						
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																						
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application																						
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis.2).																								

Date of issuance of this report 02 March 2006 (02.03.2006)	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Authorized officer  Yoshiko Kuwahara  Telephone No. +41 22 338 90 90

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

**PCT**

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

<p>Applicant's or agent's file reference <b>ONF-4933PCT</b></p>			<p><b>FOR FURTHER ACTION</b> See paragraph 2 below</p>
<p>International application No. <b>PCT/JP2004/004836</b></p>	<p>International filing date (day/month/year) <b>02.04.2004</b></p>	<p>Priority date (day/month/year) <b>03.04.2003</b></p>	
<p>International Patent Classification (IPC) or both national classification and IPC</p>			
<p>Applicant <b>ONO PHARMACEUTICAL CO., LTD.</b></p>			

<p>1. This opinion contains indications relating to the following items:</p> <p> <input checked="" type="checkbox"/> Box No. I Basis of the opinion  <input type="checkbox"/> Box No. II Priority  <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  <input type="checkbox"/> Box No. IV Lack of unity of invention  <input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement  <input type="checkbox"/> Box No. VI Certain documents cited  <input type="checkbox"/> Box No. VII Certain defects in the international application  <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application         </p> <p>2. <b>FURTHER ACTION</b></p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p>
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<p>Name and mailing address of the ISA/JP</p>	<p>Authorized officer</p>
<p>Facsimile No.</p>	<p>Telephone No.</p>

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/004836

Box No. I	Basis of this opinion
	<p>1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).</p> <p>2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> in written format</p> <p><input type="checkbox"/> in computer readable form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed.</p> <p><input type="checkbox"/> filed together with the international application in computer readable form.</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search.</p> <p>3. <input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p> <p>4. Additional comments:</p>

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/004836

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- the entire international application  
 claims Nos. 14

because:

- the said international application, or the said claims Nos. 14  
relate to the following subject matter which does not require an international preliminary examination (specify):

The subject matter described in claim 14 corresponds to a method for treatment of the human body by therapy (PCT Rule 67.1 (iv)).

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (specify):

- the claims, or said claims Nos. \_\_\_\_\_  
are so inadequately supported  
by the description that no meaningful opinion could be formed.

- no international search report has been established for said claims Nos. 14

- the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- has not been furnished  
 does not comply with the standard

the computer readable form

- has not been furnished  
 does not comply with the standard

- the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/004836

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																									
<p>1. Statement</p> <table> <tr> <td>Novelty (N)</td> <td>Claims</td> <td>1-13, 15</td> <td>YES</td> </tr> <tr> <td></td> <td>Claims</td> <td></td> <td>NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims</td> <td>1-13, 15</td> <td>YES</td> </tr> <tr> <td></td> <td>Claims</td> <td></td> <td>NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims</td> <td>1-13, 15</td> <td>YES</td> </tr> <tr> <td></td> <td>Claims</td> <td></td> <td>NO</td> </tr> </table>			Novelty (N)	Claims	1-13, 15	YES		Claims		NO	Inventive step (IS)	Claims	1-13, 15	YES		Claims		NO	Industrial applicability (IA)	Claims	1-13, 15	YES		Claims		NO
Novelty (N)	Claims	1-13, 15	YES																							
	Claims		NO																							
Inventive step (IS)	Claims	1-13, 15	YES																							
	Claims		NO																							
Industrial applicability (IA)	Claims	1-13, 15	YES																							
	Claims		NO																							
<p>2. Citations and explanations:</p> <p>The following documents were cited in the ISR:</p> <p>Document 1: Toshiaki Minami et al, Characterization of EP-receptor subtypes involved in allodynia and hyperalgesia induced by intrathecal administration of prostaglandin E<sub>2</sub> to mice, Br. J. Pharmacol, 1994, Vol. 112, p.735-740</p> <p>Document 2: EP, 860430, B1 (Ono Pharmaceutical Co., Ltd.), June 12, 2002 (12.06.02), full text</p> <p>Document 3: WO, 98-34916, A (Ono Pharmaceutical Co., Ltd.), August 13, 1998 (13.08.98), full text</p> <p>Document 1 describes the idea that the PGE<sub>2</sub> receptor subtypes EP2 and EP3 exist in the spinal cord, and the idea that PGE<sub>2</sub> triggers hyperalgesia in the spinal cord via those receptors.</p> <p>Document 2 describes the compound shown with the general formula (I) in the present international application.</p> <p>Document 3 describes the compound shown with the general formula (II) in the present international application.</p> <p>None of documents 1-3 describes or implies that the combination of a compound having an EP2 agonism and a compound having an EP2 agonism is applied for the purpose of preventing or treating spinal canal stenosis.</p> <p>Therefore, the subject matters of claims 1-13, 15 of the present international application appear to be novel and to involve an inventive step in view of documents 1-3.</p>																										

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/004836

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-3, 7-13, 15 relate to spinal canal stenosis cures having compounds defined by the required property "EP2 agonism" or "EP3 agonism" as the active ingredient. And claims 1-3, 7-13, 15 include all compounds having such properties, but only a very small portion of the claimed compounds are supported by the description in the sense of PCT Article 6, and disclosed in the sense of PCT Article 5.

And for "a compound having EP2 agonism" or "a compound having EP3 agonism", no scope of compounds having such properties can be specified even when considering the common general technical knowledge at the time of the application. Therefore, claims 1-3, 7-13, 15 do not fulfill the requirement of clarity according to PCT Article 6.

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